

#### Regulatory Affairs Proper Prescriber-Patient Relationship

#### Overview

Under federal rules and the laws of many states, in order for a prescription to be valid, there must be a proper prescriber-patient relationship. Walmart has adopted a uniform national policy that is designed to meet or exceed the federal rules and the laws of all states.

#### Proper Prescriber-Patient Relationship

In order to have a proper relationship with a patient for purposes of writing a prescription, a prescriber must:

- Document a patient evaluation that includes an appropriate medical or drug history and an in-person physical examination adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment;
- Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
- Formulate a therapeutic plan and discuss the plan, together with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
- Establish arrangements to ensure the availability of the physician or physician coverage for follow-up patient care, which usually includes a face-to-face encounter at least once a year and as often as is necessary to assure safe continuation of medication.

Established patients may not require a new history and physical examination for each new prescription, depending on good medical practice. Similarly, personal examinations might not be required when a prescriber is prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

A prescription based on an internet-based questionnaire, internet-based consultation or a telephonic consultation, without a valid preexisting prescriber-patient relationship, is invalid. A pharmacist may <u>not</u> dispense such a prescription.

March 2011 (smh) Confidential Page 1 of 4

PLAINTIFFS TRIAL EXHIBIT P-02300\_00001

## Regulatory Affairs Proper Prescriber- Patient Relationship

Indications
That a
Proper
PrescriberPatient
Relationship
May Not
Exist

Pharmacists and technicians should review each prescription carefully to determine whether it appears legitimate. The following factors **may** indicate that a proper prescriber-patient relationship does **not** exist:

- the prescription is from a doctor with an address outside the U.S.;
- the prescription was written by an out-of-state prescriber;
- the prescription was printed from an Internet link or webpage;
- the prescription was printed with a rubber-stamped signature;
- the prescription is from a prescriber writing outside the scope of his or her customary practice;
- the prescription is from an unfamiliar prescriber or practice, or the pharmacist knows the prescriber has retired or is deceased;
- the prescription is for a large quantity (especially controlled substances);
- the prescription is for a large number of a particular strength;
- the prescription has writing or markings that would indicate it was presented to, and rejected by, another pharmacy;
- the prescription is suspicious and dropped off at times when it is difficult for the prescriber to be contacted for verification (e.g. at closing or on weekends);
- The prescription is written by a doctor or for a patient for whom the pharmacy has rejected other prescriptions for a failure to have an appropriate doctor-patient relationship.

The presence of one or more of these indicators does not mean a prescription is invalid but may require investigation by the pharmacist. In addition, pharmacists must consider whether the patient and the doctor have a relationship, but the relationship is not valid because it is being used for abuse or diversion. The above list is by no means all inclusive. Pharmacists must use their professional judgment to determine when a prescription warrants verification.

### Action Required

If a pharmacist has a reasonable suspicion that a proper prescriberpatient relationship may not exist, the pharmacist must verify. A verification should include contacting the prescriber by telephone to:

- confirm the patient's name and the name and quantity of the drug prescribed;
- identify the prescriber's diagnosis;
- ask how long the prescriber has treated the patient;
- request the date of the last physical examination of the patient by the prescriber;
- verify that the prescriber performed a medical history and drug

March 2011 (smh) Confidential Page 2 of 4

# Regulatory Affairs Proper Prescriber- Patient Relationship

review of the patient; and

 ask any other questions necessary to confirm that the relationship is valid and does not exist for the purposes of abuse or diversion.

The pharmacist should also review the pharmacy's records to check if the customer has previously presented a prescription for that particular medication or from that particular prescriber. Simply because the prescriber verifies that he or she has seen the patient does not mean that an "appropriate" patient prescriber relationship exists; if other signs of an inappropriate relationship are present, the pharmacist can still exercise his or her judgment and not fill the prescription at issue.

#### Action Required (Cont'd)

If the pharmacist reasonably believes that there is a valid prescriberpatient relationship after speaking with the prescriber, the pharmacist may dispense the prescription. The pharmacist should make a notation on the prescription specifying:

- (i) the pharmacist's name,
- (ii) the name of the prescriber;
- (iii) the date of the conversation" and
- (iv) the notation "proper relationship verified."

If the pharmacist does not reasonably believe that a valid prescriber-patient relationship exists, the pharmacist may not dispense the prescription and must notify Regulatory Affairs immediately. The preferred form of notification is completion of the Forged or Fraudulent Prescription Activity Webform. This webform provides important details of the transaction so that Regulatory Affairs may take appropriate follow up action.

The pharmacist should explain to the patient that he/she is unable to fill the prescription because a proper relationship with the prescriber cannot be verified. If a situation arises where the pharmacist feels threatened or otherwise unable to complete the information requested on the webform, at a minimum the pharmacist must note the prescriber's name, the drug(s) prescribed and the time the prescription was presented at the pharmacy. This information, along with the pharmacist's name and store/club number, must be faxed to Regulatory Affairs. The pharmacist must notify Regulatory Affairs, who will assist in determining whether to notify the corresponding examining board for the prescriber or other appropriate authorities.

Failure to notify Regulatory Affairs may result in disciplinary action, up to and including termination.

March 2011 (smh) Confidential Page 3 of 4

### **Regulatory Affairs Proper Prescriber- Patient Relationship**

Notes:

At all times the pharmacist must remain courteous and professional in communications with both prescribers and patients.

Blanket refusals of prescriptions are not allowed. pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or for a valid medical reason before refusing to fill.

If the pharmacist cannot reach the prescriber, he/she should exercise professional judgment to determine whether or not to fill the prescription.

Conclusion:

Contact your Market Health and Wellness Director or Regulatory Affairs if you have any questions regarding this information.

March 2011 (smh) Confidential Page 4 of 4